EyeKare

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For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

NEPEYE™

NEPAFENAC OPHTHALMIC SUSPENSION 0.1% W/V

DOSAGE FORM : Ophthalmic Suspension

COMPOSITION :

Nepafenac 0.1% w/v, Benzalkonium chloride Solution IP (as Preservative) 0.01% v/v, Water for Injections q.s.

DESCRIPTION : Nepeye is a sterile, topical, nonsteroidal anti-inflammatory prodrug (NSAID) for ophthalmic use.

INDICATIONS : Nepeye is indicated for the treatment of pain and inflammation associated with cataract surgery.

CONTRA-INDICATIONS :

Hypersensitivity to the active substance to any of the excipients, or to any other nonsteroidal anti-inflammatory drugs (NSAIDS)

WARNINGS AND PRECAUTIONS : NOT FOR INJECTION. FOR EXTERNAL USE ONLY.

With some nonsteroidal anti-inflammatory drugs including nepafenac, there exists the potential for increased bleeding time due to interference with thrombocyte aggregation. There have been reports that ocularly applied nonsteriodal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery. Hence it is recommended that nepafenac ophthalmic suspension should be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

Topical nonsteroidal anti-inflammatory drugs (NSAIDs) including nepafenac, may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

Use of topical NSAIDs may result in keratitis in some susceptible patients, continuous use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs including nepafenac and should be closely monitored for corneal health.

Postmarketing experience with topical NSAIDs suggests that patients with complicated ocular surgeries, corneal denervation corneal epithelial defects, diabetes mellitus ocular surface diseases (e.g. dry eye syndrome), rheumatoid arthritis or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients. Postmarketing experience with topical NSAIDs also suggests that use more than 1 day prior to surgery or use beyond 14 days post surgery may increase patient risk for occurrence and severity of corneal adverse events.

Nepafenac Ophthalmic Suspension should not be administered while wearing contact lenses.

PREGNANCY & LACTATION: Reproduction studies performed with nepafenac in rabbits and rats at oral doses up to 10 mg/kg/day have revealed no evidence of teratogenicity due to nepafenac, despite the induction of maternal toxicity. At this dose, the animal plasma exposure to nepafenac and amfenac was approximately 260 and 2400 times human plasma exposure at the recommended human topical ophthalmic dose for rats and 80 and 680 times human plasma exposure for rabbits, respectively. In rats, maternally toxic doses $\geq$ 10 mg/kg were associated with dystocia, increased post-implantation loss, reduced fetal weights and growth, and reduced fetal survival. Nepafenac has been shown to cross the placental barrier in rats. There are no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, nepafenac should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Because of the known effects of prostaglandin biosynthesis inhibiting drugs on the fetal cardiovascular system (closure of the ductus arteriosus), the use of Nepeye ophthalmic suspension during late pregnancy should be avoided.

Nepafenac ophthalmic suspension is excreted in the milk of pregnant rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Nepeye is administered to a lactating woman.

DRUG INTERACTIONS: Topical nonsteroidal anti-inflammatory drugs (NSAIDs) including nepafenac, may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

Nepeye Ophthalmic Suspension may be administered in conjunction with other topical ophthalmic medications such as beta-blockers, carbonic anhydrase inhibitors, alpha-agonists, cycloplegics, and mydriatics.

ADVERSE REACTIONS: In controlled clinical studies, the most frequently reported ocular adverse events following cataract surgery were capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure, and sticky sensation. These events occurred in approximately 5 to 10% patients.

Other ocular adverse events occuring at an incidence of approximately 1 to 5% included conjunctival edema, corneal edema, dry eye, lid margin crusting ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, photophobia, tearing and vitreous detachment. Some of these events may be the consequence of the cataract surgical procedure.

Nonocular adverse events reported at an incidence of 1 to 4% included headache, hypertension, nausea/vomiting and sinusitis.

DOSAGE & ADMINISTRATION : SHAKE WELL BEFORE USE. One drop of Nepeye should be applied to the conjunctival sac of the affected eye(s) three times daily beginning 1 day prior to cataract surgery continued on the day of surgery and through the first 2 weeks of the postoperative period. Nepeye Ophthalmic Suspension may be administered in conjunction with other topical ophthalmic medications such as beta-blockers, carbonic anhydrase inhibitors, alpha-agonists, cycloplegics and mydriatics.

If more than one topical ophthalmic medicinal product is being used the medicines must be administered at least 5 minutes apart.

The dropper tip should not be allowed to touch any surface since this may contaminate the solution.

Elderly: No overall differences in safety and effectiveness have been observed between elderly and younger patients.

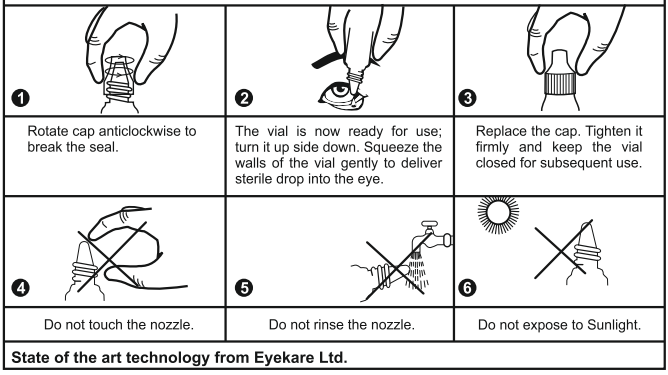
Pediatric use : Nepeye is not recommended for use in children below 10 years due to lack of data on safety and efficacy.

INCOMPATIBILITIES: None known.

PACKING : Nepeye Ophthalmic Suspension are available in 5ml in ***Iyondellbasel Purell*** low density polyethylene dispensing system consisting of plastic bottle with good flexibility. Tamper evidence ring around the closure and neck area of the bottle.

STORAGE INSTRUCTIONS : Store in cool & dry place. Protect from light.
Keep out of reach of children.
Use the solution within one month after opening the container.
For external use only.

INSTRUCTIONS FOR USE



State of the art technology from Eyekare Ltd.

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